GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:54
ANSWERED ON:18.11.2016
Use of Banned/Spurious Drugs
Manjhi Shri Hari;Tanwar Shri Kanwar Singh

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether there are reports that a number of patients have lost their lives due to administration of wrong, spurious and expired drugs by the doctors in various Government and Corporate Hospitals and if so, the details thereof and action taken thereon;

(b) whether the Government has taken note of the fact that medicines are being sold online and offline without proper prescription by the doctors inducing the chances of drug abuse and if so, the details thereof and preventive steps taken in this regard;

(c) whether the sale of spurious and expired drugs is going on unabated in small towns and villages especially in remote and far-flung areas of the country and if so, the details thereof;

(d) whether bar coding for medicines, training for drug manufacturers and zero tolerance towards sub-standard medicines is a matter of grave concern for the Government and if so, the steps taken by the Government to protect the consumer from counterfeit/sub-standard drugs being sold online and to regulate the e-pharmacy web business; and

(e) the details of drug testing laboratories and new laboratories proposed to be set up, State/UT-wise.

Answer

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a) to (e): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA
STARRED QUESTION NO. 54* FOR 18TH NOVEMBER, 2016

(a): Stray incidents of this nature get reported in the media from time to time. These are investigated by the Central and the State Governments and necessary remedial action is taken.
(b): Sale and distribution of drugs in the country is regulated under the provisions of the Drugs & Cosmetics Act, 1940 and Rules thereunder. In accordance with these Rules, drugs specified in Schedules H, H1 and X cannot be sold except on, and in accordance with the prescription of a Registered Medical Practitioner from a licensed premise. Some instances of online sale of medicines had been reported in the media. Wherever any violation is noticed, suitable action is taken by the State Licensing Authorities.
(c): No such reports of unabated sale of spurious and expired drugs in small towns and villages of the country has come to the notice of the Central Government. However, a few stray incidents are reported from time to time and action as per provisions of the law is taken in such cases.
(d): The Government is committed to ensuring that the quality, safety and efficacy of drugs are not compromised. With this in view, the Government has taken a series of measures. These include:
(i) stringent penalties including making certain offences cognizable and non-bailable;
(ii) establishment of special designated Courts for trial of offences under Drugs and Cosmetics Act for speedy disposal of cases;
(iii) announcement of a Whistle Blower Scheme to encourage vigilant public participation for detection of movement of spurious drugs in the country;
(iv) issuance of guidelines to the State Drugs Controllers for taking action on samples of drugs declared spurious, adulterated, misbranded or 'not of standard quality';
(v) instructions to the concerned staff to keep a vigil and draw samples of drugs for test and analysis for monitoring the quality of drugs moving in the country;
(vi) increase in the number of posts in the Central Drugs Standard Control Organization (CDSCO);
(vii) re-equipping of drug testing laboratories with state-of-the-art equipment;
(viii) large scale nation-wide survey to determine the 'not of standard quality' drugs;
(ix) conducting workshops and training programmes for skill enhancement in areas such as Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Distribution Practices (GDP), Good Clinical Practice (GCP) and Good Storage and Distribution Practices (GSP) to regulators and industry in partnership with other Departments, industry and regulators of other countries including USA and European Union.
(x) Conducting training programmes for laboratory personnel of State and Central laboratories to upgrade their analytical capabilities and skill sets.
(xi) risk based inspections of manufacturing facilities have been started.

Bar coding has already been started for exports. As far as bar coding for domestic supplies is concerned, a draft notification had been issued on 03.06.2015 to invite objections and suggestions from the stakeholders. The notification was, however, not finalized keeping in view the reservations of manufacturers regarding high cost of bar coding.
The issue relating to online sale of drugs has been examined by the Drug Consultative Committee (DCC) and a Sub-Committee of the DCC. The DCC has finalised its recommendations for establishment of a robust system to regulate online sale of drugs before permitting such sale.
(e): List of State drugs testing laboratories is at Annexure. Currently, there are seven Central Drug Testing Laboratories at Kolkata, Chennai, Mumbai, Chandigarh, Hyderabad, Guwahati and Kasauli. The Government has approved setting up of six more Central laboratories for drugs / cosmetics / Medical devices.
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Annexure to the Statement referred to in reply to the Lok Sabha Starred Question No. 54 for 18th November, 2016

S.NO State Name and Address of Laboratory
1 Goa Food & Drugs Laboratory, Bambolim Goa
2 Karnataka Office of Chief Scientific Officer, Drugs Testing Laboratory, Palace Road, Bangalore-560001
Office of Chief Scientific Officer, Regional Drugs Testing Laboratory, Ground Floor, 2nd Cross, 2nd Stage, Raghavendra Colony, Bellary-585101
Office of Chief Scientific Officer, Regional Drugs Testing Laboratory, Plot No. 193, Industrial Area, 2nd Stage, Raipur, Dharwad-580604
3 Kerala Drugs Testing Laboratory, Red Cross Road, Thiruvananthapuram, Pin-695035
Regional Drugs Testing Laboratory, Ernakulam
4 Himachal Pradesh Composite Testing Lab,Kandaghat,Solan,HP
5 Andhra Pradesh Drugs Control Laboratory, Siddhartha Medical College Campus, Vijaywada-520008
6 Gujarat Food and Drug Laboratory, Near Polytechnic, Vadodara
7 Tamil Nadu Government Analyst, Drugs Testing Laboratory, Teynampet(DMS Campus) Chennai- 6.
Government Analyst, Dept. of Biological Control, King Institute of Preventive Medicine Research, Guindy, Chennai- 32
8 Rajasthan Drugs testing laboratory, Mandir marg, sethi colony, Jaipur (Rajasthan)-302004
9 Puducherry Department of Food & Drug Testing, Drug Testing Laboratory, Gorimedu
10 Chattishgarh Drugs testing Laboratory, Kalibadi Raipur, Chhattisgarh-492001
11 Punjab Drug testing laboratory, Chandigarh
12 Bihar Bihar Drugs control laboratory , Agamkuan, Patna
13 Odisha State drug testing and research laboratory, Odisha, Bhubaneswar
14 Jharkhand Jharkhand state drugs testing laboratory, Namkun, Ranchi-834010.
15 Tripura State Drug Testing Laboratory, Agartala
16 Meghalaya Food & Drug Laboratory, Pesteur
Institute, Shillong, Meghalaya − 793001
17 Jammu & Kashmir Combined Food & Drug Laboratories,
Patoli Mangotrian,Jammu
18 Maharashtra Drug Control Laboratory, Survey No. 341, Bandra kurla Complex, bandra (East), 400051
Drug Control Laboratory, Third Floor, Nath Super Market, Aurangpura, Aurangabad-431001
19 Haryana Drug testing laboratory, Sector 11D, Chandigarh
20 West Bengal EFRAC, Subhash Nagar, P. O. Nilganj Bazar, Barasat, Kolkata-700121
21 Telangana Drugs Control Laboratory, Vengal Rao Nagar, Hyderabad
22 Chandigarh Drug testing laboratory, Chandigarh (The Gov. of UT Chandigarh approved Drugs Testing Laboratory of Punjab State for UT Chandigarh)
23 Uttar Pradesh Government analyst, UP O/o Food and drug testing laboratory, Sector C, Aliganj, Lucknow
24 Delhi Drug Testing Laboratory, A-20, Lawrence Road, Delhi-110035
25 Madhya Pradesh DRUG TESTING LABORATORY,
Food & Drugs Administration,
Idgah Hills, Bhopal (M.P.) − 462032
26 Uttarakhand Drug Testing Laboratory, Dehradun